

### **REMARKS**

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 34-38, 60-63 and 73-100 are pending in the subject application. Claims 1-33, 39-59 and 64-72 were previously canceled.

Claims 34-38, 60-63 and 73-100 stand rejected under 35 U.S.C. §102 and/or on grounds of non-statutory/obviousness type double patenting.

Claim 61 was amended to correct a typo and thus entry of this amendment is respectfully requested.

### **PROVISIONAL REQUEST FOR WITHDRAWAL OF FINALITY**

In the Response dated November 5, 2007, Applicants amended claims 34, 36, 38, 80, 91, 93, and 95 for clarity and so as to more distinctly claim the inventions of the subject application. For example, the arcuate implant member feature of claim 1 was amended so as to provide that the (a) arcuate implant member *has a length that is sufficient so the arcuate implant member extends in a plane between two adjacent vertebrae*, (b) the arcuate implant member has a cross-section being sized *so that portions of the arcuate implant member including ends thereof* extend through a preformed aperture that is formed in each of the two adjacent vertebrae. In other words, claim 34 as amended provides, *inter alia*, that the arcuate implant member including the portions thereof that extend through the preformed aperture extend in a plane.

The grounds for rejection does not anywhere describe how the element identified by reference numeral 10 has a length sufficient so that the arcuate implant member extends in a plane between two adjacent vertebrae and so the portions of the arcuate implant member including ends thereof that extend through a preformed aperture that is formed in each of the two adjacent vertebrae also thus extend in this plane between the adjacent vertebrae. As there is no discussion as to how Lumb shows the structure added by amendment, it is respectfully submitted

that the grounds for rejection under 35 U.S.C. §102 at least as to claim 34 are incomplete and therefore, the finality decision of the Examiner is premature. Applicants would note that the As-filed Response does indicate that other independent claims were amended so as to include the in plane language. Thus, Applicant provisional request that the finality of this Office Action be withdrawn.

Applicants would note that notwithstanding the foregoing, Applicants have addressed the §102 rejection herein including remarks as to why the amended structure is missing from the cited reference.

#### NON-STATUTORY/ OBVIOUSNESS DOUBLE PATENTING REJECTION(S)

Claims 34-38 and 73-90 stand rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-61 of U.S. Patent No. 6,607,530.

Applicants will submit a terminal disclaimer signed by applicants or a registered attorney of record that is compliance with 37 C.F.R. §§1.321(b) and 1.321 (c) after indication that all of the pending claims are in an allowable condition or upon request of the Examiner if there are no other issues barring allowance of the claims.

#### 35 U.S.C. §102 REJECTIONS

The Examiner rejected claims 34-38, 60-63 and 73-100 under 35 U.S.C. §102(b) as being anticipated by Lumb [USP 3,426,364]. Applicants respectfully traverse. Although claim 61 was amended herein, this amendment was to correct a typo. Thus, none of the features amended herein are specifically relied upon to distinguish the claimed invention from the cited prior art and thus these amendments shall not be considered as being made to overcome the cited reference. The following addresses different groupings of the claims.

As the Federal Circuit has indicated, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir.

1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the following remarks that the above identified claims are not anticipated by Lumb.

### **Claims 34-38 & 73-100**

In claim 34, Applicants claim an implantable spinal fixation system that includes an arcuate implant member. The arcuate implant member has a length that is sufficient so the arcuate implant member *extends in a plane between two adjacent vertebrae*. The arcuate implant member also has a cross-section that is sized so that portions of the arcuate implant member including ends thereof extend through a preformed aperture that is formed in each of the two adjacent vertebrae. In view of the language in claim 34, the portions of the arcuate implant member including ends thereof that extend through a preformed aperture also are in this plane as well.

The Office Action asserts that the feature identified by reference numeral 10 corresponds to the arcuate implant member of the presently claimed invention. Applicants respectfully disagree.

As can be seen from the following excerpt(s) from Lumb as well as with Reference to figures 1-4 of Lumb, the element identified by reference numeral 10 is used to designate a prosthetic vertebrae or prosthetic appliance. A description of the correspondence of features of the artificial or prosthetic vertebrae or prosthetic appliance 10 to a natural vertebrae is provided in Lumb (see col. 2, lines 58-66 thereof).

As described in Lumb, the prosthetic appliance 10 is intended to function as an artificial vertebrae and includes a generally Y-shaped element 12 that is connected to a body forming portion 14. Lumb provides that a trough 16 is cut in the connection mating surface 18 of the body forming portion 14 such that when the body forming portion is joined to divergent arms 20 of the Y-shaped element 12, a cylindrical bore 20 is thereby defined. It is further described that

the patient's spinal cord is received in the cylindrical bore. As also provided in Lumb, the body forming portion 14 is passed in front of the patient's spinal cord into the space that is left vacant when the natural vertebrae is removed from the body before the divergent arms 20 of the Y-shaped element 12 are secured to the body forming portion 14 by means of the screws 34.

As further described in Lumb, in the particular form shown in figures 1-4, the body forming portion 14 includes a pair of integrally formed ears 38 that project longitudinally from the ends of the body portion and are adapted to lap (*i.e.*, lap over) the centrum of the vertebrae adjacent to each end of the body forming portion 14 of the prosthetic appliance 10. In this regard, it should be noted that the centrum also can be referred to as the anterior solid segment or body of a natural vertebrae and is one of the two essential parts of a natural vertebrae (the other essential part is the posterior segment or arch).

These integrally formed ears 38 of the prosthetic appliance 10 are secured to the body or centrum of the respective adjacent vertebrae by means of screws 40. As shown in the figures, the construction of the prosthetic device, requires that these the screws 40 be arranged so as to be at an angle with respect to a plane that extends between the prosthetic appliance and each adjacent natural vertebrae or a plane that extends between the natural vertebrae, when it is secured to the body of the respective natural vertebrae.

The following are the above referenced excerpts from Lumb (see col. 2, line 48 - col. 3, line 46).

Referring now to the drawings for a detailed description of the present invention and, initially, to FIGURES 1-4, inclusive, for this purpose, reference numeral **10** has been employed to designate the prosthetic appliance in a general way and it will be seen to include an inverted generally Y-shaped element **12** detachably connected to a body-forming portion **14** that has a semi-cylindrical trough **16** cut in its connecting surface **18** that, when joined to the divergent arms **20** of the Y-shaped element, cooperates therewith to define a cylindrical bore **22** adapted to receive the patient's spinal cord. As aforementioned, the divergent arms **20** of the Y-shaped member **14** function in much the same manner as the neural arches **24** of the patient's natural vertebrae that have been generally referred to by reference numeral **26**; whereas, the stem portion **28** of said member takes the place of the neural spine **30** of the real bone. Body **14** of the prosthesis, on the other hand, replaces the centrum **32**.

Elements **12** and **14** of the appliance are both preferably fabricated from some type of plastic material compatible with the internal tissues and bone of the body, several such materials being commercially available for use in the fabrication of prosthetic appliances. The material must, of course, be non-toxic, able to withstand the compression and bending loads to which a vertebrate's spine is subjected without breaking, and be workable through either machining or direct moulding techniques to produce a smooth surface which will not chafe or otherwise irritate the patient's spinal cord or the pads of cartilaginous tissue that separate same from the adjacent natural vertebrae. Thermoplastic vinylidene fluoride manufactured by Pennsalt Chemicals Corporation and marketed under the trademark "Kynar" has proven quite satisfactory although there are probably several other materials that will do as well.

Dimensionally, the prosthetic device of the present invention closely approximates in overall height, width and thickness that of the vertebra it is to replace although, for a given animal species, these dimensions remain much the same so that the units can be manufactured in standard sizes. The various screws, nuts and connecting braces which will be described presently may also be fabricated from plastic materials although, from the standpoint of strength, it is desirable to make them from metal. Stainless steel is satisfactory for this purpose although these elements are preferably made from a special steel alloy containing chromium, molybdenum and nickel sold under the trademark "Vitalium" that is widely used in the fabrication of metal fittings for internal applications.

The Y-shaped member **12** is joined to the body portion **14** by means of four screws **34** (Figure 3) that pass into countersunk threaded openings **36** that extend from the arms **20** down into the body alongside spinal cord passage **22**. The body must, of course, be passed in front of the patient's spinal cord into the space left vacant by removal of the natural vertebra before the arms of the Y-shaped element can be screwed thereto from the back through an incision made for this purpose. In those instances where the centrum **32** remains intact and only the neural arch and spine must be replaced, Y-shaped element **12** may be screwed directly to the centrum after the latter has been separated from the neural arch.

The body **14**, in the particular form illustrated in FIGURES 1-4, has a pair of integrally-formed ears **38** projecting longitudinally in transversely-spaced relation from both ends thereof adapted to lap the centrum **32** of the adjacent natural vertebrae to which they are fastened by screws **40**. As revealed most clearly in FIGURES 2 and 4, the opposed inside surfaces of the ears **38** are curved to conform with the shape of the natural centrum to which they attach.

In sum, the structure of the prosthetic appliance 10 described in Lumb does not correspond to the structure of an arcuate member as set forth in claim 34 and as described in the subject application. The prosthetic appliance does not extend between two adjacent vertebrae in a plane but rather is mainly disposed in and occupies the space that is between adjacent natural vertebrae where the removed intervening natural vertebrae would have been found. Also, the arrangement and structure of the prosthetic appliance is such that the screws 40 which secure the prosthetic appliance 10 to the adjacent natural vertebrae cannot extend in a direction that is in a plane that extends between the adjacent vertebrae. Thus, the elements of the prosthetic appliance 10 are not arranged as required by the limitations of claim 34. Therefore, the prosthetic appliance 10 in Lumb does not correspond to the arcuate implant of the implantable spinal fixation system of claim 34.

As can be seen from the following further excerpt(s) from Lumb, the prosthetic appliance 10 is further secured in to the adjacent natural vertebrae by metal braces 46 that are secured both to the prosthetic appliance and to the adjacent natural vertebrae. As shown in figure 1 in Lumb, the metal braces 46 are slightly curved and include a plurality of holes or apertures 48. The plurality of apertures 48 are arranged in the metal braces 46 so they are essentially perpendicular to the long curved axis of each metal brace. In other words the aperture are transverse with respect to the direction in which the metal braces extend lengthwise.

In Lumb, the stem portion 28 of the Y-shaped element 12 includes an elongated vertical slot 42. A screw fastener 44 is received in the slot 42 and passes through one of the apertures in each of the metal braces, an aperture located at about the mid-point of each metal braces. In this way, the screw fastener 44 attaches the metal braces 46 to opposite sides of the Y-shaped element stem portion 28.

It is further provided in Lumb that the extremities of the metal braces 46 project longitudinally beyond the stem portion 28 so as to lap (*i.e.*, lap over) the neural spines or arches of the adjacent natural vertebrae. It is further described that the extremities of the metal braces are secured to the neural spines of the adjacent natural vertebrae by means of screws 50. Because of the construction of the metal braces and the arrangement of the apertures 48 therein,

the screws 50 must be arranged so as to be at an angle with respect to a plane that extends between the prosthetic appliance and each adjacent natural vertebrae or a plane that extends between the natural vertebrae, when the metal braces 46 are secured to the neural spines.

The following are the above referenced further excerpts from Lumb (see col. 3, lines 47-72).

The stem portion 28 of the Y-shaped element 12 is provided with an elongated vertical slot 42 adapted to receive a screw fastener 44 that attaches metal braces 46 to opposite sides thereof. As shown in FIGURE 1, braces 46 include a plurality of apertures 48 to receive the screws 44 and are slightly curved. In the forms shown in FIGURE 1 where the prosthetic appliance is used to bridge the gap left upon removal of only one natural vertebra, the braces are fastened on opposite sides of the stem 28 at approximately [sic] their mid-point. The extremities thereof thus project longitudinally beyond the stem in position to lap the adjacent neural spines 30 of the natural vertebrae in much the same manner as the ears 38 of the body 14 lap the centrum. These extremities are fixedly attached to the spines by screws 50 that pass through holes drilled in the latter.

As shown in FIGURE 1, the connection thus formed is a rigid one and no hinged or articulate movement takes place between the artificial vertebra and the adjacent natural vertebrae. Slot 42 in the brace 46 merely makes it possible to raise and lower the latter so that its extremities are properly located to be fastened onto the adjacent spines. The resulting rigid connection is much the same as would occur if two or more of the patient's natural vertebrae were fused, the latter being a fairly common surgical procedure for back injuries.

In sum, the metal braces 46 in Lumb that further secure the prosthetic appliance 10 to the neural spines of the adjacent natural vertebrae do not correspond to the structure of an arcuate member as set forth in claim 34. The metal braces do not extend between two adjacent vertebrae in a plane between the adjacent vertebrae. Also, the ends or extremities of the metal braces are not and cannot be extend through apertures formed in the adjacent vertebrae. In contrast to the present invention, in Lumb each of the metal braces 46 extend between the artificial vertebrae and the adjacent natural vertebrae and the extremities of the metal braces lap over structure of the natural vertebrae adjacent to the artificial vertebrae or prosthetic appliance 10. In addition to not

being disclosed, such an arrangement makes it physically impossible for the extremities of the metal braces to be received in apertures in the adjacent natural vertebrae.

It has been suggested that the screws 50 can form a part of the metal braces and thus the screws in combination with the extremities of the metal braces correspond to the portions of the arcuate member that extend through apertures in the adjacent vertebrae. In this case, it also has been asserted that the holes that were drilled in the neural spines to threadably receive the screws in Lumb correspond to the apertures in the adjacent vertebrae referred to in the claim. Ignoring for the moment whether it is proper to assert that the screw/ metal brace combination is proper, such a combination also would not yield a structure or configuration that corresponds to the limitations of the arcuate implant member of claim 34.

It is very clear from that shown and described in Lumb, that the extremities of the metal braces 46 lap over structure of the natural vertebrae adjacent to the artificial vertebrae or prosthetic appliance 10 and thus are not in apertures in the adjacent natural vertebrae. Thus, the screws 50 that pass through the apertures 48 in the metal braces 46, must be at an angle with respect to the lapped over surfaces of the vertebrae, because of this arrangement and the arrangement of the apertures 48 in the metal braces 46. Thus, it is not possible for the structure formed by the screws and metal braces in Lumb to form a structure that would be in a plane that extends between the prosthetic appliance and the adjacent natural vertebrae or the adjacent natural vertebrae.

In conclusion it is physically impossible for the prosthetic appliance 10 and metal braces 46 described in Lumb, alone or in combination, to describe, as claimed by applicants (a) an arcuate member that has a length that is sufficient so as to extend between two adjacent vertebrae, (b) an arcuate member (*i.e.*, the long axis thereof), that also extends in a plane between the adjacent vertebrae; and (c) an arcuate member that also has a cross-section that is configured so that portions of the arcuate implant member including ends thereof extend through a preformed aperture that is formed in each of the two adjacent vertebrae, where the portions of the arcuate implant member including ends thereof also would extend in the plane between the adjacent vertebrae.



Not only is there no such disclosure, Applicants also respectfully submit that there is no teaching, suggestion or motivation offered anywhere in Lumb to modify the devices or appliances described therein so as to yield the arcuate implant member of claim 34. Moreover, if the prosthetic appliance 10 or the metal braces 46 were modified so as to correspond to the limitations of the arcuate implant member of claim 34, such a modification would destroy<sup>1</sup> the intended purpose and function of these devices as described in Lumb.

Applicants respectfully submit that the foregoing remarks regarding claim 34 also at least apply to distinguish the spinal system as set forth in claim 36, the spinal fusion kit of claim 38, the method for stabilizing adjacent segments of a mammalian bone as set forth in claim 80, the spinal fixation system of claim 91, and the methods for stabilizing adjacent vertebrae of a mammalian spine as set forth in claims 93 or 95. Also, each of claims 35, 37, 73-79, 81-90, 92, 94, 96-100, depend from one of the foregoing independent claims. Thus, each of claims 35, 37, 73-79, 81-90, 92, 94, 96-100 is considered to be allowable because it depends from a base claim that is considered to be allowable. This shall not be construed as an admission that any of these claims is not otherwise patentable over Lumb.

For example, claims 80-90 are directed to stabilizing adjacent segments of a mammalian bone. The disclosure in Lumb is expressly directed to, and is thus limited to the spine and in particular the replacement of a natural vertebrae. While the spine is part of the skeletal structure of a mammal, the disclosure in Lumb is so confined to the spine and elements of the spine, it is necessarily limited by the express and implied language such that it would not be proper to assert that Lumb explicitly or inherently discloses or describes a technique for stabilizing other bones of a mammalian body.

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<sup>1</sup> As provided by the Federal circuit, a 35 U.S.C. §103 rejection based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in a reference, is not proper and the prima facie case of obviousness cannot be properly made. In short there would be no technological motivation for engaging in the modification or change. To the contrary, there would be a disincentive. *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

There also is no disclosure anywhere in Lumb of rotating an arcuate member of a size sufficient to extend in a plane between the two adjacent vertebrae from a first position to a second position such as that provided in claims 95-99 of the present invention. Such a concept is completely different from that described in Lumb, which describes replacing a natural vertebrae with a prosthetic appliance 10 and directly connecting the appliance to the adjacent vertebrae by screws 40 and also connecting the prosthetic appliance to the adjacent vertebrae by means of metal braces 46 that are secured to the prosthetic appliance by a screw fastener 44 and also are each secured to the adjacent vertebrae by screws 50. Such a construction does not in any way or fashion describe the arcuate member of the present invention.

It is respectfully submitted that claims 34-38 and 73-100 are patentable over the cited reference for the foregoing reasons.

#### **Claims 60-63**

As previously indicated by Applicants, the method as set forth in claims 60-63 is directed to process where a common channel is cut in the adjacent vertebrae (*i.e.*, in both vertebrae) using a rotating element and inserting an implant in this channel. As also set forth in the claims, the rotating element includes a midpoint that is located between the adjacent vertebrae (*i.e.*, pointing at the intervertebral space) to cut the common channel.

As can be seen from the foregoing remarks regarding claim 1, Lumb discloses a prosthetic appliance 10 that is located in the vacant space created between two vertebrae after a natural vertebrae is removed. As also indicated above, Lumb describes drilling holes in the natural vertebrae to receive screws which are used to directly secure the prosthetic appliance to the natural vertebrae's body or to directly secure the metal braces to the natural vertebrae's neural spines.

There is absolutely no discussion anywhere in Lumb that describes locating the rotating element at a midpoint that is located between adjacent vertebrae, cutting a common channel between same and then inserting an implant between the adjacent vertebrae. All that Lumb

discloses is removing a natural vertebrae using some unspecified method, replacing it with a prosthetic appliance 10 and then securing the prosthetic appliance in place using screws. In fact if the drill were located at the position set forth in the claims, it would be physically impossible for the drill to make the holes in the adjacent natural vertebrae.

It is respectfully submitted that claims 60-63 are patentable over the cited reference for the foregoing reasons.

The following additional remarks shall apply to each of the above.

In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify *corresponding elements* disclosed in the allegedly anticipating reference (emphasis added, citations in support omitted). *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, 730 F. 2d 1452, 221 USPQ 481,485 (Fed. Cir. 1984). In concluding that the '770 Patent did not anticipate the claims, the Federal Circuit in *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, at 221 USPQ 485-486, further provides that:

The '770 patent discloses an entirely different device,  
composed of parts distinct from those of the claimed invention, and  
operating in a different way to process different materials differently.

Thus, there is no possible question of anticipation by equivalents.

Citations omitted.

It is clear from the foregoing remarks, that the allegedly corresponding elements disclosed in Lumb (*e.g.*, reference numerals 10, 50) do not in fact correspond to the elements of the claimed invention. It also is clear that the prosthetic system including the arches and screws described in Lumb functions and operates in a different manner from that of the claimed invention. As also indicated above, the method disclosed and taught in Lumb for replacing a natural vertebrae with a prosthetic device and securing the prosthetic device to vertebrae adjacent to the prosthetic device

using the arches is completely different from that claimed and taught by Applicants for the arcuate member/implant and/or stabilizing adjacent vertebrae. Thus, there can be no disclosure or teaching in Lumb of Applicants' invention.

It is respectfully submitted that for the foregoing reasons, claims 34-38, 60-63 and 73-100 are patentable over the cited reference and thus satisfy the requirements of 35 U.S.C. §102(b). Therefore, these claims, including the claims dependent therefrom are allowable.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Applicants believe that additional fees are not required for consideration of the within Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,  
Edwards Angell Palmer & Dodge, LLP

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